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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

Jacques JOLIVET et al.	Conf. No. **2203**
Serial No.: 10/806,336	Group Art Unit: **1614**
Filed: March 23, 2004	Examiner: Unassigned

For: METHOD FOR ADMINISTRATION OF TROXACITABINE

INFORMATION DISCLOSURE STATEMENT UNDER 37 CFR §§ 1.56, 1.97 and 1.98

MAIL STOP AMENDMENT
Commissioner for Patents
P.O. Box 1450
ALEXANDRIA, VA 22313-1450

Sir:

This information disclosure statement is made in accordance with 37 C.F.R. §§ 1.56, 1.97 and 1.98 as follows:

Timing and Fees

☒ Under 37 C.F.R. § 1.97(b), no fee or statement is required for filing this information disclosure statement is filed:

- ☐ within three months of the filing date of a national application other than a CPA under § 1.53(d);
- ☐ within three months of the actual filing date of the national phase of a PCT application; OR
- ☒ before the mailing of a first substantive office action (including after filing of an RCE).

☐ Under 37 C.F.R. § 1.97(c), this information disclosure statement is filed after the periods specified in 37 C.F.R. § 1.97(b), but before the mailing date of:

- ☐ a final rejection under 37 C.F.R. 1.113;
- ☐ termination of prosecution, e.g. Ex Parte Quayle, M.P.E.P § 609(B)(2); OR
- ☐ a notice of allowance under 37 C.F.R. § 1.311; and

is accompanied by:

☐ the statement as specified in 37 C.F.R. § 1.97(e) set out below; OR

☐ a check covering the fee of $180.00 under 37 C.F.R. § 1.17(p).

☐ Under 37 C.F.R. § 1.97(d), this information disclosure statement is filed after the mailing date of the following actions which have not been withdrawn:

☐ a final action under 37 C.F.R. § 1.113;

☐ termination of prosecution, e.g. Ex Parte Quayle, M.P.E.P § 609(B)(2); OR

☐ a notice of allowance under 37 C.F.R. § 1.311;

AND is filed on or before payment of the issue fee; AND is accompanied by:

☐ the statement as specified in 37 C.F.R. § 1.97(e) as set forth below, and the fee of $180.00 under 37 C.F.R. § 1.17(p).

Statements Under 37 C.F.R. 1.97(e)

☐ Each item of information contained in this information disclosure statement was a first cited in a communication from a foreign patent office in a counterpart foreign application having a mailing date not more than three months prior to the filing date of this information disclosure statement; or

☐ No item of information contained in this information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and to the knowledge of the undersigned attorney after making reasonable inquiry, no item of information contained in this information disclosure statement was known to any individual designated in 37 C.F.R. § 1.56(c) more than three months prior to the filing date of the information disclosure statement.

Cited Materials

☐ Copies of materials listed but not attached were cited in benefit (35 U.S.C. § 120) ancestor application Serial No. _____, on Form 892 by the Examiner and/or Form 1449 by the applicant; see 37 C.F.R. § 1.98(d).

☒ Copies of some of the materials listed were cited in an international search report dated July 5, 2004.

☐ Copies of the materials listed are attached (except for the foregoing).

Non-English Language References

☒ An English-language search report or equivalent paper from a foreign patent office is provided indicating the relevance of cited reference(s).

☐ A foreign-language search report from a foreign patent office is provided, and pertinent parts are translated substantively below:

X = document of particular relevance when it is taken alone
Y = document of particular relevance when it is combined with another such document
A = document defining the general state of the art
O = non-written disclosure
P = intercalated document
T = document cited to understand the theory or principle underlying the invention
E = patent document which has the benefit of a date earlier than the filing date and which was published only on or after this filing date
D = cited in the application
L = cited for another reason
& = publication of member of same patent family

☐ Translation of other relevant information on foreign search report

Other Information

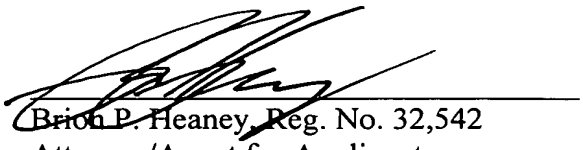
Payment of Fees Due (If Any):

☐ A check for $_____ covering the fee identified above is attached.

☐ Please charge to Deposit Account No. 13-3402 $_____ for the fee identified above.

☒ The Commissioner is hereby authorized to charge or credit any overpayment to Deposit Account #13-3402, two copies of this paper are attached for this purpose.

Respectfully submitted,



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Attorney Docket No.: STROMIX-0008

Date: October 6, 2004
BPH:rrt

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PTO/SB/08A (08-00)
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary)

Sheet 1 of 2

Complete if Known	
Application Number	10/806,336
Filing Date	March 23, 2004
First Named Inventor	Jacques JOLIVET et al.
Group Art Unit	1614
Examiner Name	Unassigned
Attorney Docket Number	STROMIX-0008

U.S. PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	U.S. Patent Document Number	Kind Code[2] (*if known*)	Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		6,630,480		Gourdeau et al.	10/7/2003	
		6,747,036		Gourdeau et al.	6/8/2004	
		5,817,667		Chu et al.	10/6/1998	
		5,270,315		Belleau et al.	12/14/1993	
		5,041,449		Belleau et al.	8/20/1991	
		6,350,753		Belleau et al.	2/26/2002	

FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Foreign Patent Document Office[3]	Number[4]	Kind Code[5] (*if known*)	Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T[6]
		WO	02/078678			10/10/2002		
		WO	02/076472			10/03/2002		
		WO	00/57861			10/5/2000		
		WO	02/30922			10/5/2000		
		WO	96/07413			3/14/1996		
		WO	92/18517			10/29/1992		

Examiner Signature		Date Considered	

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[1] Unique citation designation number. [2] See attached Kinds of U.S. Patent Documents. [3] Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). [4] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [5] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. [6] Applicant is to place a check mark if the English language Translation is attached.

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Sheet 2 of 2

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First Named Inventor	Jacques JOLIVET et al.
Group Art Unit	1614
Examiner Name	Unassigned
Attorney Docket Number	STROMIX-0008

OTHER PRIOR ART -- NON PATENT LITERATURE DOCUMENTS

Examiner Initials *	Cite No.[1]	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T[2]
		International Search Report dated June 17, 2004	
		Written Opinion of the International Searching Authority dated March 24, 2004	
		Giles F J et al: "Troxacitabine, a novel dioxolane nucleoside analog, has activity in patients with advanced leukemia" Journal of Clinical Oncology, vol. 19, no. 3, 1 February 2001 pags 762-771	
		Giles F et al: "Phase II study of Troxatyl in patients with chronic myeloid leukemia in blastic phase (CML-BP)", Blood, W.B. Saunders Company, vol. 98, no. 11, Part 2, 16 november 2001	
		Abstract #2633 Antitumor efficacy of troxacitabine given by continuous administration: The human HT-29 colon xenograft used as a tumor model. Proceedings of the American Association for Cancer Research, (1st Edition) Volume 44, Published March 2003	
		Abstract #2633 Antitumor efficacy of troxacitabine given by continuous administration: The human HT-29 colon xenograft used as a tumor model. Proceedings of the American Association for Cancer Research, (2nd Edition), Volume 44, Published July 2003	
		Poster Antitumor efficacy of (Troxatyl) troxacitabine given by continuous administration: The human HT-29 colon xenograft used as a tumor model. AACR Meeting July 2003	
		Abstract #553473 Phase I evaluation of troxacitabine (Troxatyl) administered by continuous infusion in patients with refractory acute myeloid leukemia (AML). 45th ASH Annual Meeting, abstract published August 2003	
		Poster Phase I evaluation of troxacitabine (Troxatyl) administered by continuous infusion in patients with refractory acute myeloid leukemia (AML). 45th ASH Annual Meeting, Dec. 2003	
		Poster Phase I evaluation of troxacitabine administered by continuous infusion in patients with refractory acute myeloid leukemia (AML). ASCO Meeting , June 3-8, 2004	

Examiner Signature		Date Considered	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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